Citation:

Pereira MA, Kartashov AI, Ebbeling CB, Van Horn L, Slattery ML, Jacobs DR Jr, Ludwig DS. Fast-food habits, weight gain and insulin resistance (the CARDIA study): 15-year prospective analysis. *Lancet.* 2005 Jan 1-7; 365 (9,453): 36-42. Erratum in: *Lancet.* 2005 Mar 16; 365 (9,464): 1,030.

PubMed ID: 15639678

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the association between reported fast-food habits and changes in body weight and insulin resistance over a 15-year period in the United States.

Inclusion Criteria:

- Recruitment stratification was used to obtain nearly equal numbers of participants who were: black and white, young (18-24 years) and old (25-30 years) and with more (high school or more) and less (less than high school) education
- More details regarding inclusion criteria are previously reported.

Exclusion Criteria:

- Did not come to the year 15 examination
- Missing data for fast-food, body weight or important covariates at baseline or follow-up
- Female participants who were pregnant at baseline or within 180 days of year 15, or were breastfeeding
- Suspected Type 1 diabetes based on insulin treatment.

Additional exclusion criteria for this study were previously reported.

Description of Study Protocol:

Recruitment

Recruitment for this study was previously reported.

Design

Prospective cohort study (Coronary Artery Risk Development in Young Adults, CARDIA) in which participants were followed for 15 years, and had six clinical examinations in:

- 1985-1986 (baseline or year zero)
- 1987-1988 (year two)
- 1990-1991 (year five)
- 1992-1993 (year seven)
- 1995-1996 (year 10)
- 2000-2001 (year 15).

Dietary Intake/Dietary Assessment Methodology

For dietary assessment, structured interviews were held at every CARDIA examination and included a series of questions on dietary practices, including food preparation and where meals were typically eaten.

Blinding Used

Not applicable.

Intervention

Not applicable.

Statistical Analysis

- To assess changes in fast-food intake over time and the effects of age, time, and secular trends on fast-food intake, repeated measures regression analysis was used
- General linear models were used to calculate adjusted means of demographic and lifestyle factors according to category of fast-food intake and to analyze the relationship between the independent variables (baseline fast-food frequency and 15-year change in fast-food frequency) with changes in the dependent variables (body weight and HOMA insulin resistance) over the 15-year time period.
- 15-year change in fast-food was calculated as the baseline fast-food frequency subtracted from the value of fast-food frequency at the final follow-up examination at year 15
- Potential confounding or mediating factors were modelled as their baseline value and their change over time, when available
- Model 1 included sex, age, study center and education and the baseline value of the dependent variable
- Model 2 further included alcohol consumption, smoking status, physical activity and television viewing
- Model 3 included baseline values and changes in dietary factors, including total caloric intake, dietary fiber, percentage of calories from saturated fat, unsaturated fat and daily intake of soft drinks, refined grains, whole grains, low-fat and high-fat dairy, fruits, non-starchy vegetables, meat and fish.
- Interactions between fast-food frequency and ethnic origin, sex and baseline overweight status were also examined.

Data Collection Summary:

Timing of Measurements

Participants were followed for 15 years and had six clinical examinations in:

- 1985-1986 (baseline or year zero)
- 1987-1988 (year two)
- 1990-1991 (year five)
- 1992-1993 (year seven)
- 1995-1996 (year 10)
- 2000-2001 (year 15).

Dependent Variables

- Body weight was measured by study personnel at each clinical examination
- HOMA insulin resistance was measured using fasting glucose and insulin samples.

Independent Variables

Baseline fast-food frequency and 15-year change in fast-food frequency were measured using a structured interview at each of the clinical examinations. Subjects were asked "How often do you eat breakfast, lunch or dinner at places such as McDonald's, Burger King, Wendy's, Arby's, Pizza Hut, Kentucky Fried Chicken?" Responses were recorded to the nearest frequency per week on a semi-continuous scale and classified as less than one, one-two, or greater than two.

Control Variables

Sex, age, study center, education, ethnic origin, baseline overweight status, alcohol consumption, smoking status, physical activity, television viewing, total caloric intake, dietary fiber, percentage of calories from saturated fat, unsaturated fat, and daily intake of soft drinks, refined grains, whole grains, low-fat and high-fat dairy, fruits, non-starchy vegetables, meat and fish.

Description of Actual Data Sample:

- *Initial N:* 5,115 subjects who attended the baseline examination
- *Attrition (final N):*
  - N=3,031 included in the body weight analysis
  - N=2,767 included in the HOMA insulin resistance analysis
- *Age:*
  - 18-30 years at baseline
  - Mean age 25 years
- *Ethnicity:*
  - White (N=1,587)
  - Black (N=1,444)
- *Other relevant demographics:* Not applicable
- *Anthropometrics:* Mean BMI=24.5kg/m^2
- *Location:* United States.

Summary of Results:

Fast-Food Frequency

- Year zero fast-food frequency was associated with a rise in body weight in both ethnic groups, independent of other lifestyle factors. Even after adjustment for many possible confounding factors, a difference in year zero fast-food frequency of three times per week was associated with mean gains of 2.2kg in black people (P=0.014) and 1.6kg in white people (P=0.064)
- Change in fast-food frequency over 15 years was also independently associated with changes in body weight in white people (1.8kg, P<0.001), with a weaker association in black individuals (0.7kg; P=-0.1053)
- Compared to participants with infrequent fast-food intake (less than one time per week), those with frequent (more than two times per week) consumption of fast-food gained an extra 4.5kg at follow-up (P=0.0054).

Fast-Food and Body Weight

	Fast-Food Variable	Black Subjects		White Subjects	
		b (SE)	P	b (SE)	P
Model 1	Baseline	1.44 (0.58)	0.0126	2.68 (0.47)	<0.0001
	Change	0.70 (0.40)	0.0774	2.67 (0.41)	<0.0001
Model 2	Baseline	1.72 (0.61)	0.0050	1.84 (0.50)	0.0013
	Change	0.63 (0.42)	0.1004	1.97 (0.42)	<0.001
Model 3	Baseline	2.22 (0.72)	0.0014	1.56 (0.55)	0.0064
	Change	0.74 (0.45)	0.1053	1.84 (0.44)	<0.0001

Fast-Food and Insulin Resistance

- The association between year zero fast-food intake and change in insulin resistance in black and white individuals that was noted in model 2 was no longer apparent in model 3 after adjustment for many dietary factors that may have been confounders
- Changes in fast-food was directly associated with changes in insulin resistance in both black and white people even after adjusting for potentially confounding factors
- Compared to participants with infrequent fast-food intake (less than one time per week), those with frequent (more than two times per week) consumption of fast-food gained had a 104% greater increase in insulin resistance at follow-up (P=0.0083).

	Fast-Food Variable	Black Subjects		White Subjects	
		b (SE)	P	b (SE)	P
Model 1	Baseline	0.09 (0.14)	0.5011	0.32 (0.10)	0.0008
	Change	0.26 (0.10)	0.0061	0.37 (0.08)	<0.0001
Model 2	Baseline	0.22 (0.14)	0.0688	0.17 (0.10)	0.0056
	Change	0.29 (0.09)	0.0015	0.28 (0.09)	<0.0001
Model 3	Baseline	0.13 (0.16)	0.4112	0.04 (0.11)	0.7596
	Change	0.32 (0.10)	0.0021	0.23 (0.09)	0.0127

Author Conclusion:

Fast-food consumption has strong positive associations with weight gain and insulin resistance, suggesting that fast-food increases the risk of obesity and Type 2 diabetes.

Reviewer Comments:

- *This study is observational in nature, which limits definitive conclusions about causality*
- *Reliance on self-reported diet and other lifestyle factors introduces measurement error.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes

2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes

5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes

8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	No
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes